

Sheet 1 of 4

FORM PTO-1449 (Modified)

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE **STATEMENT** 

**APPLICANT** Banerjee et al.

18025-1013

ATTY. DOCKET NO.

FILING DATE **GROUP** June 22, 2001 1614

SERIAL NO.

09/887,281

#### U.S. PATENT DOCUMENTS

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	В	5	0	3	3	2	5	2	07/23/91	Carter	53	425	07/30/90
	С	5	0	5	2	5	5	8	10/01/91	Carter	206	439	07/27/90
	D	5	3	2	3	9	0	7	06/28/94	Kalvelage	206	531	03/15/93
	E	5	5	2	5	6	2	3	06/11/96	Spear et al	514	423	03/11/94
	F	5	6	0	2	1	1	0	02/11/97	Drumm et al	514	47	01/26/95
	G	5	6	5	4	2	7	6	08/05/97	Barrett et al	514	13	06/07/95
	Н	5	6	6	8	1	1	0	09/16/97	Barrett et al	514	13	06/07/95
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	М	5	6	9	1	3	3	6	11/25/97	Dorn et al	514	236.2	09/08/95
	N	5	7	3	3	5	2	6	03/31/98	Trevino et al	424	9.52	12/14/95
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	Q	5	7	9	5	5	6	4	08/18/98	Aberg et al	424	45	03/07/96
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	υ	5	9	6	5	6	2	2	10/12/99	Senanayake	514	653	06/23/98
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le	х	6	0	4	0	3	4	4	03/21/00	Gao et al	514	554	05/21/98

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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE	APPLICANT Banerjee <i>et al.</i>	2 0 20 TER 16	
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### U.S. PATENT DOCUMENTS

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		AA	6	0	7	1	9	7	1	06/06/00	Senanayake	514	653	05/05/99
		AB	6	1	2	6	9	1	9	10/03/00	Stefely et al	424	45	02/07/97
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# OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

Tel	AI	Bartow and Brogden, "An Update of its Pharmacological Properties and Therapeutic Efficacy in the Management of Asthma," <i>Drugs</i> , <u>55(2):</u> 303-322 (1998)
	AJ	Campbell et al, "A comparison of the efficacy of long-acting B2-agonists: eformoterol via Turbohaler(R) and salmeterol via pressurized metered dose inhaler or Accuhaler (R), in mild to moderate asthmatics," Respiratory Medicine, 93:236-244 (1999)
	AK	Dellamary et al, "Hollow Porous Particles in Metered Dose Inhalers," Pharmaceutical Research, 17(2):168-174 (2000)
	AL	Derwent# 000971705, WPI Acc. No. 1973-48969U/197335 citing German Patent Application No. DE 2305092 A, "Alpha-aminomethylbenzyl alcohol derivsprepd. by redn. of corresponding protected derivs."
Cu	АМ	Ekstrom et al, "Low-dose formoterol Turbuhaler(R) (Oxis(R)) b.i.d., a 3-month placebo- controlled comparison with terbutaline (q.i.d.)," <i>Respiratory Medicine</i> , 92:1040-1045 (1998)

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PATENT &	<u> </u>	AN	Kaumann and Lemoine, "Direct labelling of myocardial B1-adrenoceptors; Comparison of binding affinity of 3H-()-bisoprolol with its blocking potency," <i>Archives of Pharmacology</i> , 331:27-39 (1985)
		AO	Lecaillon et al, "Pharmacokinetics and tolerability of formoterol in healthy volunteers after a single high dose of Foradil dry powder Inhalation via aerolizer (TM)," European Journal Clinical Pharmacology, 55:131-138 (1999)
		АР	Lemoine et al, "Direct labelling of B2-adrenoceptors; Comparison of binding potency of 3H-ICI 118,551 and blocking potency of ICI 118,551," Archives of Pharmacology, 331:40-51 (1985)
		ΔQ	Lotvall <i>et al</i> , "Similar bronchodilation with formoterol delivered by Aerolizer or Turbuhaler," <i>Can Respir J</i> , 6(5):412-416 (1999)
		AR	Nielsen <i>et al</i> , "Flow-dependent effect of formoterol dry-powder inhaled from the Aeolizer (R)," <i>Eur Respir J</i> , 10:2105-2109 (1997)
		AS	Nightingale <i>et al</i> , "Differential Effect of Formoterol on Adenosine Monophosphate and Histamine Reactivity in Asthma," <i>Am J Respir Crit Care Med</i> , 159:1786-1790 (1999)
		AT	Nogrady, T., (editor), Medicinal Chemistry: A Biochemical Approach, Oxford University Press, New York, pgs. 388-392 (1985)
		ΑU	Palmqvist et al, "Inhaled dry-powder formoterol and salmeterol in asthmatic patients: onset of action, duration of effect and potency," Eur Respir J, 10:2484-2489 (1997)
		AV	Rico-Mendez <i>et al</i> , "Formoterol en polvo seco, dos veces al dia versus salbutamol aerosol, cuatro veces al dia, en pacientes con asma estable," <i>Revista Alergia Mexico</i> , XLVI(5):130-135 (1999)
		AX	Ringdal et al, "Onset and duration of action of single doses of formoterol inhaled via Turbuhaler(R)," Respiratory Medicine, 92:1017-1021 (1998)
		AY	Schreurs et al, "A dose-repsonse study with formoterol Turbuhaler(R) as maintenance therapy in asthmatic patients," Eur Respir J, 9:1678-1683 (1996)
		AZ	Seberova and Andersson, "Oxis(R) (formoterol given by Turbuhaler(R)) showed as rapid an onset of action as salbutamol given by a pMDI," <i>Respiratory Medicine</i> , <u>94:</u> 607-611 (2000)
		ВА	Selroos et al, "Delivery Devices for Inhaled Asthma Medication," Clin Immunother, 6:273-299 (1996)
<u>We</u>	v	ВВ	Tomioka <i>et al</i> , "Anti-Allergic Activities of the B-Adrenoceptor Stimulant Formoterol (BD 40A)," <i>Arch Int Pharmacodyn</i> , <u>250:</u> 279-292 (1981)

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PATENT BC 1	Totterman et al, "Tolerability to high doses of formoterol and terbutaline via Turbuhaler(R) for 3 days in stable asthmatic patients," Eur Respir J, 12:573-579 (1998)
	Ullman <i>et al</i> , "Formoterol inhaled as dry powder or via pressurized metered-dose inhaler in a cumulative dose-response study," <i>Allergy</i> , 51:745-748 (1996)

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ATTY. DOCKET NO. 18025-1013

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**APPLICANT** Banerjee et al.

FILING DATE June 22, 2001

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Kw			'Flovent", Glaxo Wellcome Inc., <u>Physicians' Desk Reference</u> , 54th ed., (2000), pp. 1186- I 189											
Ver	_		Warne, P.J., "The discovery and clinical development of RPR 106541: an airway-selective steroid for the treatment of asthma", <i>Emerging Drugs</i> , 5(2):231-239 (2000)											

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	нΙ	4	3	3	5	1	2	1	06/15/82	Phillipps et al.	424	241	02/13/81
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	J	5	1	2	6	3	7	5	06/30/92	Skidmore et al.	514	651	11/29/90
	К	5	2	2	5	4	4	5	07/06/93	Skidmore <i>et al.</i>	514	651	02/19/92
	L	5	2	7	0	3	0	5	12/14/93	Palmer	514	171	09/03/91
	М	5	2	9	0	8	1	5	03/01/94	Johnson <i>et al.</i>	514	651	11/25/91
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X\* = English Language Derwent Abstract is provided.

## OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

tu	N)	CG	Barnes, P.J., "Scientific rationale for inhaled combination therapywith long-acting $\theta_2$ -agonists and corticosteroids," <i>Eur. Respir. J.</i> 19: 182-191 (2002)
		СН	Campestrini <i>et al.</i> , "Automated and sensitive method for the determination of formoterol in human plasma by high-performance liquid chromatography and electrochemical detection," <i>Journal of Chromatography B</i> 704: 221-229 (1997)
		С	Cazzola et al., "Long-Acting $\theta_2$ -Agonists in the Treatment of Acute Exacerbations of COPD," Clin. Drug Invest. 22(6): 369-376 (2002)
	Sw	СJ	Derwent#010743444, WPI Acc No.:1996-240399/199625 for German Patent Application DE 19541689, "Medicament contg. ciclesonid and beta2-sympathomimetic - for treating chromic obstructive respiratory disease,"

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO. SERIAL NO. 18025-1013 09/887,281				
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE	APPLICANT Banerjee <i>et al.</i>				
STATEMENT	FILING DATE June 22, 2001	GROUP 1614			

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

		THEN ANY (Including Author, Title, Date, Fertillett Fages, Etc.)
New	СК	Derwent#012030009, WPI Acc No.:1998-446919-199838 for PCT Patent Application WO 98/34595, "Pressurised liquid aerosol propellant for pharmaceutical inhalerscontains carbon dioxide and hydro-fluoroalkane; gives more consistent dosing and a better particle size spectrum,"
	CL	Derwent#013011051, WPI Acc No.:2000-182903/200016 for PCT Patent Application WO 00/06121, "Aerosol propellant comprising dinitrogen monoxide and hydrofluoroalkane and optionally containing a pharmaceutically active substance,"
	СМ	Derwent#013023586, WPI Acc No. 2000-195437/200017, for PCT Patent Application WO 00/07567 "Aerosol formulation for drug administration, containing small amount of cromoglycate or nedocromil salt as drug carrier, to improve dispersion stability and accuracy of dosing,"
	CN	Derwent#013024375, WPI Acc No.: 2000-196226/200018 for German Patent Application DE 19835346, "Two-part drug capsule for use in powder inhalers is formed from hydrophobic plastics, preferably high density polyethylene,"
	CO	Derwent#013227765, WPI Acc No. 2000-399639/200034, for PCT Patent Application, WO 00/28979 "Use of magnesium stearate for stabilization of dry powder inhalation formulations to improve resistance to moisture,"
	СР	Derwent#013790372, WPI Acc No.: 2001-274583/200129, for PCT Patent Application, WO 01/22956 "Drug combination of soft steroid and beta-2-adrenoceptor agonist, administered by inhalation for effective treatment of respiratory or allergic diseases, e.g. asthma,"
	ca	Derwent#014808338, WPI Acc No.:2002-629044/200268, for PCT Patent Application, WO 02/060533 "Medicament containing a betamimetic and an oxitropium salt useful for the treatment of respiratory disorders with reduced side effects,"
	CR	Derwent#014816787, WPI. Acc No.: 2002-637493/200269, for PCT Patent Application, WO 02/060532 "Medicament containing a betamimetic and an ipratropium salt useful for the treatment of respiratory disorders with reduced side effects,"
	cs	Eickelberg et al., "Ligand-independent Activation of the Glucocorticoid Receptor by $6_2$ -Adrenergic Receptor Agonists in Primary Human Lung Fibroblasts and vascular Smooth Muscle Cells," <i>The Journal of Biological Chemistry</i> 274(2): 1005-1010 (1999)
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NO	CU	Greening et al., "Added salmeterol versus higher-dose corticosteroid in asthma patients with symptoms on existing inhaled corticosteroid," <i>The Lancet</i> 344: 219-224 (1994)

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_	0	W	cv	Grootendorst <i>et al.</i> , "Effect of oral prednisolone on the bronchoprotective effect of formoterol in patients with persistent asthma," <i>Eur. Respir. J.</i> <u>17:</u> 374-379 (2001)
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/			DA	Lipworth <i>et al.</i> , "Effects of Treatment with Formoterol on Bronchoprotection against Methacholine," <i>Am. J. Med.</i> 104: 431-438 (1998)
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			DD	Oddera <i>et al.</i> , "Salmeterol Enhances the Inhibitory Activity of Dexamethasone on Allergen-Induced Blood Mononuclear Cell Activation," <i>Respiration</i> 65: 199-204 (1998)
			DE	Package Insert for: ADVAIR™ DISKUS http://fb.a-files.net/PackageInsert/Advair.htm (acessed on 09/26/02) (Copyright, 1999 Glaxo Wellcome Inc.)
_			DF	Palmqvist <i>et al.</i> , "Onset of Bronchodilation of Budesonide/Formoterol vs. Salmeterol/Fluticasone in Single Inhalers," <i>Pulmonary Pharmacology &amp; Therapeutics</i> 14: 29-34 (2001)
			DG	Pang, L. and A.J. Knox, "Regulation of TNF- $\alpha$ -induced eotaxin release from cultured human airway smooth muscle cells by $\theta_2$ -agonists and corticosteroids," <i>FASEB J.</i> 15: 261-269 (2001)
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W	D	วา	Schreurs <i>et al.</i> , "A dose-response study with formoterol Turbuhaler™ as maintenance therapy in asthmatic patients," <i>Eur. Respir. J.</i> <u>9:</u> 1679-1683 (1996)			
1 1		ΣK	Seldon et al., "Albuterol Does Not Antagonize the Inhibitory Effect of Dexamethasone on Monocyte Cytokine Release," Am. J. Respir. Crit. Care Med. <u>157:</u> 803-809 (1998)			
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	D	N	Stewart <i>et al.</i> , "Acute formoterol administration has no argogenic effect in nonasthmatic athletes," <i>Medicine &amp; Science In Sports &amp; Exercise</i> 34(2): 213-217 (2002)			
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